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BRADLEY N. RUBEN, PC 463 FIRST ST, SUITE 5A HOBOKEN, NJ 07030			EXAMINER WALKER, AMANDA H	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/544,260

Applicant(s)

BLUNN ET AL.

Examiner

AMANDA H. WALKER

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-35 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 03 August 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

Claims 1, 4, 5, 8, 11, 13, 20-24, 27, 28, and 31-34 are amended.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-18, 20-28 and 31-35, are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Positive recitations of human parts are as follows:

A. The following claims positively recite the bodily fluids in the joint space: 1, 28, and 31 and dependents.

B. The following claims positively recite the surface of the reamed acetabulum: 4, 5, 21, 22, 33, and 34 and dependents.

C. The following claims recite the surface of the acetabulum and the surrounding joint space: 18, 20, 32, and 35 and dependents.

Thus, claims 1-18, 20-28 and 31-35 include a human part within the scope of the invention and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F. 2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 3 are indefinite for failing to further limit the structure of the kit. These claims are directed to limitations that further define the method step and not the product.

Claim 8, "continuous/contiguous" is indefinite. The two terms are not equivalent and it is not clear what applicant intends with the provision of the "slash".

Claims 9 and 10, "gel/hydrogel" is indefinite. The two terms are not equivalent and it is not clear what applicant intends with the provision of the "slash".

Claim 11 is indefinite. The grouping is not in proper Markush Format.

Claim 12, there is no antecedent support for "the surface"

Claims 14 and 15 are indefinite. The groupings are not in proper Markush Format.

Claims 18 and 35 are indefinite. Is applicant claiming that the radius, diameter, volume, surface area is bigger?

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Claims 1 and claim 20 are duplicative. Though claim 20 defines the head as "having a size and shape" while claim 1 defines the head as "having a radius of curvature", claim 20 further defines the size as "radius of curvature". The remaining functional language fails to further distinguish the structure of the claims.

Claims 21, 22, 26, 33 and 34, there is no antecedent support for "the surface".

Claim 25, "continuous/contiguous" is indefinite. The two terms are not equivalent and it is not clear what applicant intends with the provision of the "slash".

Claim 32 is indefinite. The preamble is directed to a kit yet the claim only contains one element. Definition of a kit requires more than one element.

Claims 18, 20-27 and 32-35 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The use of parentheses in claims 18, 20, 32 and 35 render the claims indefinite. The metes and bounds of the claim cannot be positively ascertained. It is not clear if the terms within the parentheses serve to further define the term adjacent thereto or merely provide one example of the adjacent term.

Claims 18, 20, 32, and 35 recite "the size (radius of curvature) of the reamer... being at most approximately 5mm greater than that of a femoral head". The radius of curvature is a measurement defining the sharpness of a curve, and therefore only indirectly related to the size of the device. Therefore, it is difficult to interpret which dimension Applicant wishes to claim. In

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addition, the lack of any recitation of the reamer being spheroid further adds to the obscurity of these claims.

Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 recites "selecting the contact area between the reamer and the femoral head such that..." in lines 9-10. This is indefinite because while the reamer and femoral head do not appear to have contacting surfaces.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson (U.S. Patent No. 2,785,673).

Regarding Claims 1-3: Anderson teaches surgical kit for hemiarthroplasty procedure. The kit has a prosthetic femoral head (FIGS 1-20) that is sized and shaped appropriately with reference to the weight of a patient (5:15-20). This would implicitly include the radius of curvature, which is related to the size of the femoral ball. Anderson also teaches a reamer (FIG. 18). The reamer is capable of reaming a socket until the cancellous bone is exposed. The size of the femoral head is complementary to the size of the reamer.

Claim Rejections - 35 USC § 102/35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 28 and 31 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Anderson (U.S. Patent No. 2,785,673), as evidenced by Rushfeld et al. and Ishihara et al.

Regarding Claim 28: The method for performing this procedure is taught by Anderson. In addition to providing a prosthetic head and reamer, Anderson teaches reaming a socket (8:65-70) and fitting the femoral head into the socket. Reaming would inherently expose cancellous bone, considering that the outer layer of cortical bone is thin.

Anderson does not elaborate on the type of pressures that would be exerted through his invention. However, it is believed that these pressures are inherent to the device, considering the benefits of mimicking the natural hydrostatic pressures at the hip. If not inherent, at the time of the invention, it would have been obvious to a person having ordinary skill in the art to optimize the invention in order to mimic the natural pressures found in the acetabulum, which are in the range of 0.01-5 MPa (see Rushfeld et al., p 414, in the caption found describing FIG.

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3a, as well as p. 414, column 3, para. 2). Furthermore, it was known at the time of the invention that these types of pressures are effective for stimulating the formation of new cartilage matrix (see Ishihara et al., abstract).

Regarding Claim 31: Anderson teaches a surgical procedure and a method of making a surgical kit comprising: providing a prosthetic femoral head and a complementary reamer (FIG. 16 and 17) that is reamer is inherently adapted to ream cancellous bone (considering that it can ream through the denser cortical bone), and determining the patient's weight (implicit to all medical procedures).

Anderson does not explicitly teach estimating the contact area of the hip joint needed to ensure hydrostatic pressure in range of 0.01-5 MPa and picking an appropriate femoral head to apply such a pressure. However, it is believed that this step would be inherent given the benefits of mimicking the natural hydrostatic pressures at the hip. If not inherent, at the time of the invention, it would have been obvious to a person having ordinary skill in the art to use a femoral head that is sized appropriately to induce such a broad range of pressure, and one would have been motivated to do so in order to provide a comfortable fit and mimic the natural pressures that occur in that particular joint space (see rejection to claim 28 supra).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18, 20, 32, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson (U.S. Patent No. 2,785,673).

Regarding Claims 18, 20, and 32: Considering that Applicant claims any clearance in the range of 0-5 mm, at the time of the invention, it would have been obvious to a person having ordinary skill in the art to ensure that the reamer was as close in size to the prosthetic femoral head as possible, and optimally the same size, for the sake of the patient's comfort, recovery time, and eventual success of the implant. The claim to the actual "clearance" is rejected under 35 USC 101 above as improperly claiming the body. Furthermore, the claim to the size (radius of curvature) is addressed in the 112 rejections supra.

Regarding Claim 35: See rejection to claims 18, 20, and 32 supra.

Claims 1, 5, 20, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan et al. (United States Patent Number 6,660,040) in view of Anderson (United States Patent Number 2,785,673).

Regarding Claims 1 and 5: Chan et al. teaches a surgical kit for hemiarthroplasty (FIG. 11) comprising a prosthetic femoral head (FIG. 11) with dimensions (including radius of curvature) that adapt to the patient's bone structure (10:55+). The surface of the femoral head has spacers (FIG. 11).

Chan et al. does not directly teach that the dimensions are adapted to the patient's body weight. However, at the time of the invention, it would have been obvious to a person having ordinary skill in the art to take the patient's body type into account when selecting a femoral head size, and one would have been motivated to do so to ensure that the femoral head is strong enough to accommodate the patient.

Chan et al. also does not elaborate on the type of pressures that would be exerted through his invention. However, at the time of the invention, it would have been obvious to a person having ordinary skill in the art to optimize the invention in order to mimic the natural pressures found in the acetabulum, which are in the range of 0.01-5 MPa (see Rushfeld et al., p 414, in the caption found describing FIG. 3a, as well as p. 414, column 3, para. 2). Furthermore, it was known at the time of the invention that these types of pressures are effective for stimulating the formation of new cartilage matrix (see Ishihara et al., abstract).

Chan et al. also does not explicitly teach a reamer that is complementary to the femoral head. However, Anderson teaches a surgical kit for hemiarthroplasty that also comprises a complementary reamer. Chan et al. and Anderson are combinable because they are from the same field of endeavor, namely, hip hemiarthroplasties. At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the kit taught by Chan et al. with the reamer taught by Anderson, and one would have been motivated to do so in times where the patient's natural acetabular socket is inadequately sized to hold the prosthetic femoral head (Anderson, 6:70+).

Regarding Claims 20 and 32: Considering that Applicant claims any clearance in the range of 0-5 mm, at the time of the invention, it would have been obvious to a person having ordinary skill in the art to ensure that the reamer was as close in size to the prosthetic femoral head as possible, and optimally the same size, for the sake of the patient's comfort, recovery time, and eventual success of the implant. The claim to the actual "clearance" is rejected under 35 USC 101 above as improperly claiming the body.

Claims 4, 6, 8-12, 14, 16, 21, 23, 25, 26, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson (U.S. Patent No. 2,785,673) as applied to claim 1, 20, and 32 above and further in view of Brown et al. (WO-02/50242-A2).

Anderson teaches the basic claimed surgical kit as applied above.

Regarding Claims 4, 6, 8, 14, 16, 21, 23, 25, and 33: Anderson does not teach a membrane with all of the limitations and properties listed in the instant claims. However, Brown et al. teaches a resorbable (p.12: line 17) **implantable** (p. 4, lines 30+ and p. 5, lines 1-5) continuous, porous membrane (FIG. 1). The membrane is adapted to deliver growth factors/stem cells/fibroblasts or chondrocytes (p.3: lines 2-10). Since the membrane may be made of collagen gel (FIG 4, p.12: lines 30-32, and p.13: lines 1-5), it is implicitly flexible and thus able to cover an articulating surface such as a femoral head. Anderson and Brown et al. are combinable because they are from the same field of endeavor, namely, biocompatible implants (p. 4, lines 30+ and p. 5, lines 1-5). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the femoral head taught by Anderson by covering it with the membrane taught by Brown et al., and one would have been motivated to do so in order to encourage cartilage growth since Brown et al. suggests addition of chondrocytes to the membrane (p. 1: lines 1-10 and p. 3, lines 2-10).

Regarding Claims 7 and 24: Brown et al. teaches the membrane/spacer. However, Brown et al. does not teach that the spacer is provided in pieces and therefore, multiple spacers. However, at the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the spacer taught by Brown et al. by dividing it into multiple pieces, and one would have been motivated to do so in order to provide greater surface area for body cells to invade and attach to the material. Additionally, duplication of parts found in the prior art is not considered to be an improvement of patentable distinction (MPEP 2144.04 VI B)

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Regarding Claims 9-12 and 26: Anderson does not teach a membrane with all of the limitations and properties listed in the instant claims. However, Brown et al. teaches a membrane that has fibrous materials enclosed within a collagen gel (FIG 4, p.12: lines 30-32, and p.13: lines 1-5). The gel is inherently deformable and it is implicit that one would adjust the size of Anderson's femoral head to maintain a natural hydrostatic pressure, as stated in the rejection to Claim 1 above. At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the femoral kit taught by Anderson with the membrane taught by Brown et al., and one would have been motivated to do so in order to encourage tissue growth (p. 1: lines 1-10).

Claims 13, 15, 17, 22, 27, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan et al. (United States Patent Number 6,660,040) in view of Anderson (United States Patent Number 2,785,673) as applied to claims 5, 20, and 32 above, and further in view of Brown et al. (WO-02/50242-A2).

Chan et al. does not teach a membrane with all of the limitations and properties listed in the instant claims. However, Brown et al. teaches a resorbable (p.12: line 17) **implantable** (p. 4, lines 30+ and p. 5, lines 1-5) continuous, porous membrane (FIG. 1). The membrane is adapted to deliver growth factors/stem cells/fibroblasts or chondrocytes (p.3: lines 2-10). Since the membrane may be made of collagen gel (FIG 4, p.12: lines 30-32, and p.13: lines 1-5), it is implicitly flexible (more so than the metal spacers of Chan et al.) and thus able to cover an articulating surface such as a femoral head. Chan et al. and Brown et al. are combinable because they are from the same field of endeavor, namely, biocompatible implants (Brown et al, p. 4, lines 30+ and p. 5, lines 1-5). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the femoral head taught by Chan et al. by

covering it with the membrane taught by Brown et al., and one would have been motivated to do so in order to encourage cartilage growth since Brown et al. suggests addition of chondrocytes to the membrane (p. 1: lines 1-10 and p. 3, lines 2-10).

Claim 19, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mosseri (U.S. Patent No. 6,231,611) in view of Averill et al. (U.S. Patent No. 5,593,451).

Mosseri teaches a surgical kit with a modular reamer (FIG. 3) having a shaft and substantially part spherical heads with cutting teeth. The head and shaft are separable (FIG. 1). The cutting teeth may face outwardly or inwardly (FIG. 3 and FIG. 6). Mosseri further teaches a reaming procedure for a ball and socket joint (FIGS. 1-18), comprising forming an access tunnel in a natural ball part of joint (FIG. 1), providing a modular shell reamer having a separable substantially part-spherical head and a shaft (FIG. 1), introducing the shaft into the tunnel and introducing the reamer head separately (FIG. 1), coupling the inserted shaft and head in situ (FIG. 2), and reaming both the socket surface and the ball surface (FIGS. 3 and 6).

Mosseri does not teach that the outward and inward cutting teeth are on the same reamer. However, at the time of the invention, it would have been obvious to a person having ordinary skill in the art to make the two separate reamers integral in order to save money on materials (MPEP 2144.04 V B). The placement of the guide arm 7 would obviously have to be modified to accommodate this convenient combination.

Response to Arguments

Applicant's arguments with respect to claims 1-34 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMANDA H. WALKER whose telephone number is (571)270-3296. The examiner can normally be reached on 8-5, M-Th, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AHW
4-29-08

/DAVID J ISABELLA/
Supervisory Patent Examiner, Art Unit 3774